

K112953

510(k) Summary

FEB - 3 2012

Teratech Corporation

Terason t3000™ Ultrasound System

1. Sponsor:

Teratech Corporation
77-79 Terrace Hall Ave.
Burlington, MA 01803

Contact Person: Ben Chiampa
Director of Quality Assurance
Telephone: 781-270-4143

Date Prepared: August 15, 2011

Date Modified February 1, 2012

2. Device Name

Proprietary Name: Terason t3000 Ultrasound System
Common / Usual Name: Diagnostic Ultrasound System
Classification Name: Diagnostic Ultrasound Transducer

(21 CFR 892.1570, 90-ITX)
Ultrasonic Pulsed Echo Imaging System
(21 CFR 892.1560, 90-IYO)
Diagnostic Ultrasonic Transducer
(21 CFR 892.1570, 90-ITX)

3. Predicate Device

Terason™ Echo/t3000 Ultrasound System (K080234)

4. Intended Use

The Teratech Corporation Terason t3000™ is a general purpose Ultrasound System intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Fetal, Abdominal, Intra-operative (abdominal, thoracic and PV); Pediatrics, Small Organ (Breast, testes, thyroid); Neonatal and Adult

Cephalic; Trans-rectal and Trans-vaginal; Musculo-skeletal (Conventional and Superficial); Cardiac (Adult & Pediatric); Peripheral Vascular.

5. Device Description

The Terason t3000 is a modified version of the Echo/t3000 Ultrasound System. The modifications include the addition of 6 new transducers (12L5A, 4V2A, 12HL7, 8EC4A, 8EC4V, and 10V5S) and improved needle guidance technology components developed by SOMA Access Systems LLC and integrated into the Terason 10V5S transducer.

6. Technology Characteristics

The design and construction of the Terason t3000 is similar to the Terason™ Echo/t3000 Ultrasound system. These systems utilize a laptop computer running Windows to run the ultrasound application and a custom designed engine for control of the acoustic array and processing of the return echoes. The engine is housed in a compartment that is attached to the bottom of the laptop.

The differences between the Terason t3000 and the Terason Echo/t3000 Ultrasound System (the predicate device) include the following:

- Six new transducers have been added to the system. The software has been modified to control these transducers and ensure compliance to the standards controlling acoustic and thermal power.
- An improved needle guidance technology is provided with the 10V5S transducer. An array of Hall Effect sensors with a data capture board is integrated into the body of the 10V5S transducer. The sensors track the position of the needle by sensing and determining the position of a magnet located on the needle. This information is transferred through the Terason engine to the application software that generates a graphic overlay upon the ultrasound image showing the position of the tip of the needle to the ultrasound acquired target. The needle tip is a virtual highlight, providing the user with a real time position update, making it easier to insert the needle in the intended target in the first attempt. This improvement is intended to result in significant reductions of multiple insertions, adjustments of needle position during insertions and resultant trauma, infections and ancillary complications from less adequate methods of needle guidance. The needle guidance software component that produces the graphic overlay of needle position is developed by Soma Access

Systems LLC of Greenville, S.C. and integrated into the Terason t3000 ultrasound software application.

B1. Non Clinical Tests

The Terason t3000 system has been tested for compliance to the following standards (with the corresponding report referenced for each standard).

- IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety.
 - Intertek Test Record Number 3157933BOX-001A
- IEC 60601-1-1, Medical Electrical Equipment Part 1: General Requirements for Safety Collateral Standard: Safety Requirements for Medical Electrical Systems.
 - Intertek Project: 9157933BOX-001B
- IEC60601-1-4 (2000), Collateral Standard: Safety Requirements for Medical Electrical Systems
 - Intertek Project: 9157933BOX-001C
- IEC 60601-2-37 / EN60601-2-37 Medical Electrical Equipment Part 2: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.
 - Transducer Model 12L5A: Intertek Report Number 9157933BOX-001E
 - Transducer Model 12HL7: Intertek Report Number 9157933BOX-001F
 - Transducer Model 4V2A: Intertek Report Number 9157933BOX-001N
 - Transducer Model 8EC4A: Intertek Report Number 9157933BOX-001L
 - Transducer Model 8EC4V: Intertek Report Number 3157933BOX-001K
 - Transducer Model 10V5S: Intertek Report Number 9157933BOX-001S

- NEMA UD 3 Acoustic Output Display
Terason t3000/Echo Ultrasound System User Guide (16-3031-15)
- Biocompatibility Tests, ISO 10993 Part 5 and Part 10
 - Biocompatibility reports for the six new transducers included in this submission.



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

TERATECH Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

FEB - 3 2012

Re: K112953

Trade/Device Name: Terason t3000 Ultrasound System with updated Needle Guidance
Graphics

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: January 20, 2012

Received: January 23, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Terason t3000 Ultrasound System with updated Needle Guidance Graphics, as described in your premarket notification:

Transducer Model Number

4V2A
5C2A
7L3V
8BP4

8EC4A
8EC4V
8MC3
10V5

10V5S
12L5A
12HL7
12L5V

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

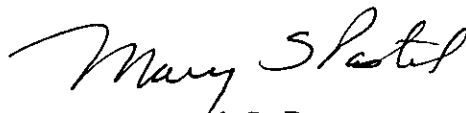
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Camille Vidal at (301) 796-2645.

Sincerely Yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use Form

510(k) Number (if known): K112953

Device Name: Terason t3000 Ultrasound System with updated Needle Guidance Graphics

Indications for Use:

The subject-modified device is a general purpose Ultrasound System intended for use by a qualified physician for the evaluation by ultrasound imaging or fluid-flow analysis of the human body. Specific clinical applications and exam types include: Fetal, Abdominal, Intra-Operative (spec. and Neuro), Laparoscopic, Pediatric, Small Organ (breast, testes, thyroid), Neonatal and Adult Cephalic, Trans-rectal, Trans-vaginal, Musculo-skeletal (Conventional and Superficial), Cardiac (adult and pediatric), and Peripheral Vascular.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE OF NEEDED)

Concurrence of CDRH, Office on In Vitro Diagnostic Devices (OIVD)

Mary S. Patel

Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

510(k) K112953

System: Terason t3000 Ultrasound System

Transducer: (see comments)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | |
|-----------------------------|---|-------------------|------------------|------------------|------------------|----------------------------|-----------------------------|--------------------|
| General (Track I Only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Dopp ^a | Comb. Modes ^b | Other ^c |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal ⁿ | P ^{1,4} | P ^{2,4} | P ^{2,4} | | P ^{2,4} | P ^{2,4} | P ^{2,4} |
| | Abdominal ^d | P ^{1,4} | P ^{2,4} | P ^{2,4} | P ⁷ | P ^{2,4} | P ^{2,4} | P ^{2,4} |
| | Intra-operative (Spec.) ^{d,e} | P ^{4,8} | P ^{4,8} | P ^{4,8} | | P ^{4,8} | P ^{4,8} | P ^{4,8} |
| | Intra-operative (Neuro) | P ⁵ | P ⁵ | P ⁵ | | P ⁵ | P ⁵ | P ⁵ |
| | Laparoscopic | P ⁶ | P ⁶ | P ⁶ | | P ⁶ | P ⁶ | P ⁶ |
| | Pediatric ^d | P ^{1,4} | P ^{2,4} | P ^{2,4} | P ⁷ | P ^{2,4} | P ^{2,4} | P ^{2,4} |
| | Small Organ (Thyroid, Breast, Testes, etc.) ^d | P ^{2,4} | P ^{2,4} | P ^{2,4} | | P ^{2,4} | P ^{2,4} | P ^{2,4} |
| | Neonatal Cephalic ^d | P ^{1,4} | P ^{2,4} | P ^{2,4} | P ⁷ | P ^{2,4} | P ^{2,4} | P ^{2,4} |
| | Adult Cephalic ^d | P ^{1,4} | P ^{2,4} | P ^{2,4} | P ⁷ | P ^{2,4} | P ^{2,4} | P ^{2,4} |
| | Trans-rectal ^f | P ^{2,4} | P ^{3,4} | P ^{3,4} | | P ^{3,4} | P ^{3,4} | P ^{3,4} |
| | Trans-vaginal ^g | P ^{2,4} | P ^{3,4} | P ^{3,4} | | P ^{3,4} | P ^{3,4} | P ^{3,4} |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | |
| | Musculo-skel. (Convent.) ^d | P ^{2,4} | P ^{2,4} | P ^{2,4} | | P ^{2,4} | P ^{2,4} | P ^{2,4} |
| | Musculo-skel. (Superfic) ^d | P ^{2,4} | P ^{2,4} | P ^{2,4} | | P ^{2,4} | P ^{2,4} | P ^{2,4} |
| | Intra-luminal | | | | | | | |
| | Other (Specify) | | | | | | | |
| Cardiac | Cardiac Adult | P ^{1,8} | P ^{2,8} | P ^{2,8} | P ^{7,8} | P ^{2,8} | P ^{2,8} | P ^{2,8} |
| | Cardiac Pediatric | P ^{1,8} | P ^{2,8} | P ^{2,8} | P ^{7,8} | P ^{2,8} | P ^{2,8} | P ^{2,8} |
| | Trans-esoph. (Cardiac) | | | | | | | |
| | Other (Specify) | | | | | | | |
| Peripheral Vessel | Peripheral vessel ^d | P ^{1,4} | P ^{2,4} | P ^{2,4} | | P ^{2,4} | P ^{2,4} | P ^{2,4} |
| | Other (Specify) | | | | | | | |

N= new indication; P= previously cleared by FDA (incl. K080234); E= added under Appendix E

^a Includes Color Dopp. (CD), Directional Power Dopp. (DPD), and (non-directional) Power Dopp. (PD).

^b B+M; B+PWD; B+CD; B+DPD; B+PD

^c Harmonic Imaging (HI)

^d Incl. ultrasound guidance for placement of needles, catheters

^e Abdominal organs and peripheral vessel.

^f Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

^g Incl. ultrasound guidance of transvaginal-biopsy, infertility monitoring of follicle development.

^h Incl. guidance of amniocentesis, infertility monitoring of follicle development.

ⁱ Incl. stress echo.

¹ System uses previously cleared under K992505 with 3MHz Model L3 (Linear)

² System uses previously cleared under K012191

³ System uses previously cleared under K010883

⁴ System uses previously cleared under K030191

⁵ System uses previously cleared under K040840

⁶ System uses previously cleared under K043278

⁷ System uses previously cleared under K051334

⁸ System uses previously cleared under K080234

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary Stahl

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112953

System: Terason t3000 Ultrasound System

Transducer: 4V2A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | |
|-----------------------------|---|-------------------|---|-----|-----|----------------------------|-----------------------------|--------------------|
| General (Track I Only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Dopp ^a | Comb. Modes ^b | Other ^c |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal ⁿ | N | N | N | | N | N | N |
| | Abdominal ^d : | N | N | N | | N | N | N |
| | Intra-operative (Spec.) ^{d,e} | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric ^d : | N | N | N | | N | N | N |
| | Small Organ (Thyroid, Breast, Testes, etc.) ^d : | | | | | | | |
| | Neonatal Cephalic ^d : | N | N | N | | N | N | N |
| | Adult Cephalic ^d : | N | N | N | | N | N | N |
| | Trans-rectal ^f : | | | | | | | |
| | Trans-vaginal ^g : | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | |
| | Musculo-skel. (Convent.) ^d : | | | | | | | |
| | Musculo-skel. (Superfic) ^d : | | | | | | | |
| | Intra-luminal | | | | | | | |
| | Other (Specify) | | | | | | | |
| Cardiac | Cardiac Adult | N | N | N | | N | N | N |
| | Cardiac Pediatric | N | N | N | | N | N | N |
| | Trans-esoph. (Cardiac) | | | | | | | |
| | Other (Specify) | | | | | | | |
| Peripheral Vessel | Peripheral vessel ^d : | | | | | | | |
| | Other (Specify) | | | | | | | |

N= new indication; P= previously cleared by FDA; E= added under Appendix E

^a Includes Color Dopp. (CD), Directional Power Dopp. (DPD), and (non-directional) Power Dopp. (PD).

^b B+M; B+PWD; B+CD; B+DPD; B+PD

^c Harmonic Imaging (HI)

^d Incl. ultrasound guidance for placement of needles, catheters

^e Abdominal organs and peripheral vessel.

^f Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

^g Incl. ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

^h Incl. guidance of amniocentesis, infertility monitoring of follicle development.

ⁱ Incl. stress echo.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary Spatol
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) 6112953

System: Terason t3000 Ultrasound System

Transducer: 5C2A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | |
|-----------------------------|---|-------------------|---|-----|-----|----------------------------|-----------------------------|--------------------|
| General (Track I Only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Dopp ^a | Comb. Modes ^b | Other ^c |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal ⁿ | E | E | E | | E | E | E |
| | Abdominal ^d | E | E | E | | E | E | E |
| | Intra-operative (Spec.) ^{d,e} | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric ^d | E | E | E | | E | E | E |
| | Small Organ (Thyroid, Breast, Testes, etc.) ^d | | | | | | | |
| | Neonatal Cephalic ^d | | | | | | | |
| | Adult Cephalic ^d | | | | | | | |
| | Trans-rectal ^f | | | | | | | |
| | Trans-vaginal ^g | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | |
| | Musculo-skel. (Convent.) ^d | | | | | | | |
| | Musculo-skel. (Superfic) ^d | | | | | | | |
| | Intra-luminal | | | | | | | |
| | Other (Specify) | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | |
| | Other (Specify) | | | | | | | |
| Peripheral Vessel | Peripheral vessel ^d | E | E | E | | E | E | E |
| | Other (Specify) | | | | | | | |

N= new indication; P= previously cleared by FDA; E= added under Appendix E

^a Includes Color Dopp. (CD), Directional Power Dopp. (DPD), and (non-directional) Power Dopp. (PD).

^b B+M; B+PWD; B+CD; B+DPD; B+PD

^c Harmonic Imaging (HI)

^d Incl. ultrasound guidance for placement of needles, catheters

^e Abdominal organs and peripheral vessel.

^f Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

^g Incl. ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

^h Incl. guidance of amniocentesis, infertility monitoring of follicle development.

ⁱ Incl. stress echo.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S. Patel

Division Sign-off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 6112953

System: Terason t3000 Ultrasound System

Transducer: 7L3V

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | |
|-----------------------------|---|-------------------|---|-----|-----|----------------------------|-----------------------------|--------------------|
| General (Track I Only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Dopp ^a | Comb. Modes ^b | Other ^c |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal ⁿ | | | | | | | |
| | Abdominal ^d | E | E | E | | E | E | E |
| | Intra-operative (Spec.) ^{d,e} | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric ^d | E | E | E | | E | E | E |
| | Small Organ (Thyroid, Breast, Testes, etc.) ^d | E | E | E | | E | E | E |
| | Neonatal Cephalic ^d | E | E | E | | E | E | E |
| | Adult Cephalic ^d | E | E | E | | E | E | E |
| | Trans-rectal ^f | | | | | | | |
| | Trans-vaginal ^g | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | |
| | Musculo-skel. (Convent.) ^d | E | E | E | | E | E | E |
| | Musculo-skel. (Superfic.) ^d | E | E | E | | E | E | E |
| | Intra-luminal | | | | | | | |
| | Other (Specify) | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | |
| | Other (Specify) | | | | | | | |
| Peripheral Vessel | Peripheral vessel ^d | E | E | E | | E | E | E |
| | Other (Specify) | | | | | | | |

N= new indication; P= previously cleared by FDA; E= added under Appendix E

^a Includes Color Dopp. (CD), Directional Power Dopp. (DPD), and (non-directional) Power Dopp. (PD).

^b B+M; B+PWD; B+CD; B+DPD; B+PD

^c Harmonic Imaging (HI)

^d Incl. ultrasound guidance for placement of needles, catheters

^e Abdominal organs and peripheral vessel.

^f Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

^g Incl. ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

^h Incl. guidance of amniocentesis, infertility monitoring of follicle development.

ⁱ Incl. stress echo.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S. Pacht
Division Sign-off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 6112953

System: Terason t3000 Ultrasound System

Transducer: 8BP4

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | |
|-----------------------------|---|-------------------|---|-----|-----|----------------------------|-----------------------------|--------------------|
| General (Track I Only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Dopp ^a | Comb. Modes ^b | Other ^c |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal ⁿ | | | | | | | |
| | Abdominal ^d : | | | | | | | |
| | Intra-operative (Spec.) ^{d,e,i} | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric ^d : | | | | | | | |
| | Small Organ (Thyroid, Breast, Testes, etc.) ^d : | | | | | | | |
| | Neonatal Cephalic ^d : | | | | | | | |
| | Adult Cephalic ^d : | | | | | | | |
| | Trans-rectal ^f : | E | E | E | | E | E | E |
| | Trans-vaginal ^g : | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | |
| | Musculo-skel. (Convent.) ^d : | | | | | | | |
| | Musculo-skel. (Superfic.) ^d : | | | | | | | |
| | Intra-luminal | | | | | | | |
| | Other (Specify) | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | |
| | Other (Specify) | | | | | | | |
| Peripheral Vessel | Peripheral vessel ^d : | | | | | | | |
| | Other (Specify) | | | | | | | |

N= new indication; P= previously cleared by FDA; E= added under Appendix E

^a Includes Color Dopp. (CD), Directional Power Dopp. (DPD), and (non-directional) Power Dopp. (PD).

^b B+M; B+PWD; B+CD; B+DPD; B+PD

^c Harmonic Imaging (HI)

^d Incl. ultrasound guidance for placement of needles, catheters

^e Abdominal organs and peripheral vessel.

^f Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

^g Incl. ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

^h Incl. guidance of amniocentesis, infertility monitoring of follicle development.

ⁱ Incl. stress echo.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112953

System: Terason t3000 Ultrasound System

Transducer: 8EC4A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | |
|-----------------------------|---|-------------------|---|-----|-----|----------------------------|-----------------------------|--------------------|
| General (Track I Only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Dopp ^a | Comb. Modes ^b | Other ^c |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal ⁿ | N | N | N | | N | N | N |
| | Abdominal ^d : | | | | | | | |
| | Intra-operative (Spec.) ^{d,e} | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric ^d : | | | | | | | |
| | Small Organ (Thyroid, Breast, Testes, etc.) ^d : | | | | | | | |
| | Neonatal Cephalic ^d : | | | | | | | |
| | Adult Cephalic ^d : | | | | | | | |
| | Trans-rectal ^f : | N | N | N | | N | N | N |
| | Trans-vaginal ^g : | N | N | N | | N | N | N |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | |
| | Musculo-skel. (Convent.) ^d : | | | | | | | |
| | Musculo-skel. (Superfic) ^d : | | | | | | | |
| | Intra-luminal | | | | | | | |
| | Other (Specify) | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | |
| | Other (Specify) | | | | | | | |
| Peripheral Vessel | Peripheral vessel ^g : | | | | | | | |
| | Other (Specify) | | | | | | | |

N= new indication; P= previously cleared by FDA; E= added under Appendix E

^a Includes Color Dopp. (CD), Directional Power Dopp. (DPD), and (non-directional) Power Dopp. (PD).

^b B+M; B+PWD; B+CD; B+DPD; B+PD

^c Harmonic Imaging (HI)

^d Incl. ultrasound guidance for placement of needles, catheters

^e Abdominal organs and peripheral vessel.

^f Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

^g Incl. ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

^h Incl. guidance of amniocentesis, infertility monitoring of follicle development.

ⁱ Incl. stress echo.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S. Patel
Division Sign-off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 6112953

System: Terason t3000 Ultrasound System

Transducer: 8EC4V

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | |
|-----------------------------|---|-------------------|---|-----|-----|----------------------------|-----------------------------|--------------------|
| General (Track I Only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Dopp ^a | Comb. Modes ^b | Other ^c |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal ^h | N | N | N | | N | N | N |
| | Abdominal ^d : | | | | | | | |
| | Intra-operative (Spec.) ^{d,a} | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric ^d : | | | | | | | |
| | Small Organ (Thyroid, Breast, Testes, etc.) ^d : | | | | | | | |
| | Neonatal Cephalic ^d : | | | | | | | |
| | Adult Cephalic ^d : | | | | | | | |
| | Trans-rectal ⁱ : | N | N | N | | N | N | N |
| | Trans-vaginal ^g : | N | N | N | | N | N | N |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | |
| | Musculo-skel. (Convent.) ^d : | | | | | | | |
| | Musculo-skel. (Superfic) ^d : | | | | | | | |
| | Intra-luminal | | | | | | | |
| | Other (Specify) | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | |
| | Other (Specify) | | | | | | | |
| Peripheral Vessel | Peripheral vessel ^d : | | | | | | | |
| | Other (Specify) | | | | | | | |

N= new indication; P= previously cleared by FDA; E= added under Appendix E

^a Includes Color Dopp. (CD), Directional Power Dopp. (DPD), and (non-directional) Power Dopp. (PD).

^b B+M; B+PWD; B+CD; B+DPD; B+PD

^c Harmonic Imaging (HI)

^d Incl. ultrasound guidance for placement of needles, catheters

^e Abdominal organs and peripheral vessel.

^f Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

^g Incl. ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

^h Incl. guidance of amniocentesis, infertility monitoring of follicle development.

ⁱ Incl. stress echo.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary Speth

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) R112953
of _____

System: Terason t3000 Ultrasound System

Transducer: 8MC3

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | |
|-----------------------------|---|-------------------|---|-----|-----|----------------------------|-----------------------------|--------------------|
| General (Track I Only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Dopp ^a | Comb. Modes ^b | Other ^c |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal ^h | E | E | E | | E | E | E |
| | Abdominal ^d : | | | | | | | |
| | Intra-operative (Spec.) ^{d,e} | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric ^d : | E | E | E | | E | E | E |
| | Small Organ (Thyroid, Breast, Testes, etc.) ^d : | E | E | E | | E | E | E |
| | Neonatal Cephalic ^d : | E | E | E | | E | E | E |
| | Adult Cephalic ^d : | E | E | E | | E | E | E |
| | Trans-rectal ^f : | | | | | | | |
| | Trans-vaginal ^g : | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | |
| | Musculo-skel. (Convent.) ^d : | | | | | | | |
| | Musculo-skel. (Superfic) ^d : | | | | | | | |
| | Intra-luminal | | | | | | | |
| | Other (Specify) | | | | | | | |
| Cardiac | Cardiac Adult | E | E | E | | E | E | E |
| | Cardiac Pediatric | E | E | E | | E | E | E |
| | Trans-esoph. (Cardiac) | | | | | | | |
| | Other (Specify) | | | | | | | |
| Peripheral Vessel | Peripheral vessel ^d : | E | E | E | | E | E | E |
| | Other (Specify) | | | | | | | |

N= new indication; P= previously cleared by FDA; E= added under Appendix E

^a Includes Color Dopp. (CD), Directional Power Dopp. (DPD), and (non-directional) Power Dopp. (PD).

^b B+M; B+PWD; B+CD; B+DPD; B+PD

^c Harmonic Imaging (HI)

^d Incl. ultrasound guidance for placement of needles, catheters

^e Abdominal organs and peripheral vessel.

^f Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

^g Incl. ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

^h Incl. guidance of amniocentesis, infertility monitoring of follicle development.

ⁱ Incl. stress echo.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Postel
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K112953

System: Terason t3000 Ultrasound System

Transducer: 10V5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | |
|-----------------------------|---|-------------------|---|-----|-----|----------------------------|-----------------------------|--------------------|
| General (Track I Only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Dopp ^a | Comb. Modes ^b | Other ^c |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal ⁿ | | | | | | | |
| | Abdominal ^d : | | | | | | | |
| | Intra-operative (Spec.) ^{d,e,j} | P | P | P | | P | P | P |
| | Intra-operative (Neuro) | P | P | P | | P | P | P |
| | Laparoscopic | | | | | | | |
| | Pediatric ^d : | P | P | P | | P | P | P |
| | Small Organ (Thyroid, Breast, Testes, etc.) ^d : | P | P | P | | P | P | P |
| | Neonatal Cephalic ^d : | P | P | P | | P | P | P |
| | Adult Cephalic ^d : | P | P | P | | P | P | P |
| | Trans-rectal ^f : | | | | | | | |
| | Trans-vaginal ^g : | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | |
| | Musculo-skel. (Convent.) ^d : | | | | | | | |
| | Musculo-skel. (Superfic) ^d : | | | | | | | |
| | Intra-luminal | | | | | | | |
| | Other (Specify) | | | | | | | |
| Cardiac | Cardiac Adult | P | P | P | | P | P | P |
| | Cardiac Pediatric | P | P | P | | P | P | P |
| | Trans-esoph. (Cardiac) | | | | | | | |
| | Other (Specify) | | | | | | | |
| Peripheral Vessel | Peripheral vessel ^d : | | | | | | | |
| | Other (Specify) | | | | | | | |

N= new indication; P= previously cleared by FDA (incl. K040840; E= added under Appendix E

^a Includes Color Dopp. (CD), Directional Power Dopp. (DPD), and (non-directional) Power Dopp. (PD).

^b B+M; B+PWD; B+CD; B+DPD; B+PD

^c Harmonic Imaging (HI)

^d Incl. ultrasound guidance for placement of needles, catheters

^e Abdominal organs and peripheral vessel.

^f Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

^g Incl. ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

^h Incl. guidance of amniocentesis, infertility monitoring of follicle development.

ⁱ Incl. stress echo.

^j System uses previously cleared under K040840

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary Spatel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112953

System: Terason t3000 Ultrasound System

Transducer: 10V5S

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | |
|-----------------------------|---|-------------------|---|-----|-----|----------------------------|-----------------------------|--------------------|
| General (Track I Only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Dopp ^a | Comb. Modes ^b | Other ^c |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal ^h | | | | | | | |
| | Abdominal ^d : | N | N | N | | N | N | |
| | Intra-operative (Spec.) ^{d,e,i} | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric ^d : | N | N | N | | N | N | |
| | Small Organ (Thyroid, Breast, Testes, etc.) ^d : | N | N | N | | N | N | |
| | Neonatal Cephalic ^d : | N | N | N | | N | N | |
| | Adult Cephalic ^d : | N | N | N | | N | N | |
| | Trans-rectal ^f : | | | | | | | |
| | Trans-vaginal ^g : | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | |
| | Musculo-skel. (Convent.) ^d : | N | N | N | | N | N | |
| | Musculo-skel. (Superfic) ^d : | N | N | N | | N | N | |
| | Intra-luminal | | | | | | | |
| | Other (Specify) | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | |
| | Other (Specify) | | | | | | | |
| Peripheral Vessel | Peripheral vessel ^d : | N | N | N | | N | N | |
| | Other (Specify) | | | | | | | |

N= new indication; P= previously cleared by FDA; E= added under Appendix E

^a Includes Color Dopp. (CD), Directional Power Dopp. (DPD), and (non-directional) Power Dopp. (PD).

^b B+M; B+PWD; B+CD; B+DPD; B+PD

^c Harmonic Imaging (HI)

^d Incl. ultrasound guidance for placement of needles, catheters

^e Abdominal organs and peripheral vessel.

^f Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

^g Incl. ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

^h Incl. guidance of amniocentesis, infertility monitoring of follicle development.

ⁱ Incl. stress echo.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary Spott
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K112953

System: Terason t3000 Ultrasound System

Transducer: 12L5A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | |
|-----------------------------|---|-------------------|---|-----|-----|----------------------------|-----------------------------|--------------------|
| General (Track I Only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Dopp ^a | Comb. Modes ^b | Other ^c |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal ^h | | | | | | | |
| | Abdominal ^d : | N | N | N | | N | N | N |
| | Intra-operative (Spec.) ^{d,a} | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric ^d : | N | N | N | | N | N | N |
| | Small Organ (Thyroid, Breast, Testes, etc.) ^d : | N | N | N | | N | N | N |
| | Neonatal Cephalic ^d : | N | N | N | | N | N | N |
| | Adult Cephalic ^d : | N | N | N | | N | N | N |
| | Trans-rectal ⁱ : | | | | | | | |
| | Trans-vaginal ^g : | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | |
| | Musculo-skel. (Convent.) ^d : | N | N | N | | N | N | N |
| | Musculo-skel. (Superfic) ^d : | N | N | N | | N | N | N |
| | Intra-luminal | | | | | | | |
| | Other (Specify) | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | |
| | Other (Specify) | | | | | | | |
| Peripheral Vessel | Peripheral vessel ^d : | N | N | N | | N | N | N |
| | Other (Specify) | | | | | | | |

N= new indication; P= previously cleared by FDA; E= added under Appendix E

^a Includes Color Dopp. (CD), Directional Power Dopp. (DPD), and (non-directional) Power Dopp. (PD).

^b B+M; B+PWD; B+CD; B+DPD; B+PD

^c Harmonic Imaging (HI)

^d Incl. ultrasound guidance for placement of needles, catheters

^e Abdominal organs and peripheral vessel.

^f Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

^g Incl. ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

^h Incl. guidance of amniocentesis, infertility monitoring of follicle development.

ⁱ Incl. stress echo.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel
Division Sign-off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112953

Page 1 of ____

System: Terason t3000 Ultrasound System

Transducer: 12HL7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | |
|-----------------------------|---|-------------------|---|-----|-----|----------------------------|-----------------------------|--------------------|
| General (Track I Only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Dopp ^a | Comb. Modes ^b | Other ^c |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal ^h | | | | | | | |
| | Abdominal ^d : | | | | | | | |
| | Intra-operative (Spec.) ^{d,a} | N | N | N | | N | N | N |
| | Intra-operative (Neuro) | N | N | N | | N | N | N |
| | Laparoscopic | N | N | N | | N | N | N |
| | Pediatric ^d : | N | N | N | | N | N | N |
| | Small Organ (Thyroid, Breast, Testes, etc.) ^d : | N | N | N | | N | N | N |
| | Neonatal Cephalic ^d : | | | | | | | |
| | Adult Cephalic ^d : | | | | | | | |
| | Trans-rectal ^f : | | | | | | | |
| | Trans-vaginal ^g : | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | |
| | Musculo-skel. (Convent.) ^d : | N | N | N | | N | N | N |
| | Musculo-skel. (Superfic) ^d : | N | N | N | | N | N | N |
| | Intra-luminal | | | | | | | |
| | Other (Specify) | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | |
| | Other (Specify) | | | | | | | |
| Peripheral Vessel | Peripheral vessel ^g : | N | N | N | | N | N | N |
| | Other (Specify) | | | | | | | |

N= new indication; P= previously cleared by FDA; E= added under Appendix E

^a Includes Color Dopp. (CD), Directional Power Dopp. (DPD), and (non-directional) Power Dopp. (PD).

^b B+M; B+PWD; B+CD; B+DPD; B+PD

^c Harmonic Imaging (HI)

^d Incl. ultrasound guidance for placement of needles, catheters

^e Abdominal organs and peripheral vessel.

^f Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

^g Incl. ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

^h Incl. guidance of amniocentesis, infertility monitoring of follicle development.

ⁱ Incl. stress echo.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Patel
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K112953

System: Terason t3000 Ultrasound System

Transducer: 12L5V

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | |
|-----------------------------|---|-------------------|---|-----|-----|----------------------------|-----------------------------|--------------------|
| General (Track I Only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Dopp ^a | Comb. Modes ^b | Other ^c |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal ⁿ | | | | | | | |
| | Abdominal ^d : | E | E | E | | E | E | E |
| | Intra-operative (Spec.) ^{d,e} | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric ^d : | E | E | E | | E | E | E |
| | Small Organ (Thyroid, Breast, Testes, etc.) ^d : | E | E | E | | E | E | E |
| | Neonatal Cephalic ^d : | E | E | E | | E | E | E |
| | Adult Cephalic ^d : | E | E | E | | E | E | E |
| | Trans-rectal ^f : | | | | | | | |
| | Trans-vaginal ^g : | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | |
| | Musculo-skel. (Convent.) ^d : | E | E | E | | E | E | E |
| | Musculo-skel. (Superfic) ^d : | E | E | E | | E | E | E |
| | Intra-luminal | | | | | | | |
| | Other (Specify) | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | |
| | Other (Specify) | | | | | | | |
| Peripheral Vessel | Peripheral vessel ^d : | E | E | E | | E | E | E |
| | Other (Specify) | | | | | | | |

N= new indication; P= previously cleared by FDA; E= added under Appendix E

^a Includes Color Dopp. (CD), Directional Power Dopp. (DPD), and (non-directional) Power Dopp. (PD).

^b B+M; B+PWD; B+CD; B+DPD; B+PD

^c Harmonic Imaging (HI)

^d Incl. ultrasound guidance for placement of needles, catheters

^e Abdominal organs and peripheral vessel.

^f Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

^g Incl. ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

^h Incl. guidance of amniocentesis, infertility monitoring of follicle development.

ⁱ Incl. stress echo.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S. Pastel
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112953